IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE ACTIQ SALES AND MARKETING PRACTICES LITIGATION	:	**CIVIL ACTION NO. 07-4492**

MEMORANDUM OPINION

Tucker, C. J. **July 21, 2014**

This putative class action suit, filed pursuant to 28 U.S.C. § 1332, arises from the alleged losses sustained by the Pennsylvania Turnpike Commission and the Indiana Carpenters Welfare Fund (collectively, "Plaintiffs") for allegedly excessive payments made to Defendant Cephalon, Inc. ("Cephalon"). Plaintiffs allege that Cephalon engaged in unlawful marketing of Actiq, a drug approved by the U.S. Food and Drug Administration ("FDA") for use by oncologists trained to prescribe Schedule II opioids to treat persistent pain in cancer patients. Specifically, Plaintiffs allege that as third party payors ("TPPs") for prescriptions of Actiq, they suffered monetary losses through the payment of excessive prescription costs for treatment of conditions not approved by the FDA and for whom a wide array of less expensive pain management drugs were appropriate. The excessive Actiq prescription costs shouldered by Plaintiffs were allegedly caused by Cephalon's marketing and sale of the drug for purposes other than those approved by the FDA.

This matter is before the Court on Cephalon's Motion to Exclude the Declaration and

Testimony of Dr. Meredith Rosenthal, Plaintiffs' damages expert. In its motion, Cephalon challenges Dr. Rosenthal's expert opinion, and seeks to exclude her declaration and testimony under the admissibility requirements of Federal Rule of Evidence 702 and the principles espoused in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). Upon consideration of the parties' motions with briefs and exhibits, and following oral argument presented on July 24, 2013, the Court will deny Cephalon's Motion to Exclude for the reasons set forth below.

I. FACTUAL BACKGROUND

The factual background of this matter was previously set forth in detail in the Court's March 23, 2011 Memorandum Opinion. In re Actiq Sales & Mktg. Practices Litig., 2011 U.S. Dist. LEXIS 30749, 2011 WL 1103796 (E.D.Pa. Mar. 23, 2011). The Court therefore only discusses those facts relevant to the instant motion.

Actiq is a Schedule II drug containing the highly addictive substance fentanyl, which makes it a drug with an associated risk of fatal overdose. (Am. Compl. ¶¶ 13, 25, 27.) In November 1998, the FDA granted restricted marketing approval for Actiq, limiting Cephalon's marketing to cancer patients experiencing pain "with malignancies who had developed a tolerance to less dangerous therapies." (Am. Compl. ¶ 27.) Furthermore, the FDA specified that Actiq should not be marketed for off-label uses, stating that the drug "must not be used in opioid non-tolerant patients" and must be prescribed solely to cancer patients by oncologists and pain specialists specifically trained in the use of Schedule II opioids to treat pain in cancer patients. (Am. Compl. ¶ 27.)

In 2000, Cephalon generated $15 million in revenue from the sale of Actiq. The revenue realized by Cephalon increased sharply, so that by 2005 sales reached $412 million, making Actiq the second highest selling drug sold by Cephalon. (Am. Compl. ¶ 34.) On September 6, 2006, the FDA further narrowed the scope of Actiq by placing an additional warning on its label indicating the dangerousness of the drug, and its potential for abuse, misuse, or diversion. (Am. Compl. ¶ 32.) Plaintiffs contend that this explosion in Actiq sales was due to Cephalon's illegal marketing scheme of targeting physicians "lacking experience in the use of Schedule II opioids and the treatment of cancer patients, and to patients without malignant cancer or a history of resistance to safer pain medication." (Am. Compl. ¶ 35.)

In the instant Motion to Exclude, Cephalon challenges the qualifications, reliability, and "fit" of Dr. Rosenthal's expert opinion. Dr. Rosenthal holds a Ph.D. in health economics from Harvard University and is a Professor of Health Economics and Policy at the Harvard School of Public Health. Dr. Rosenthal's research concerns the economics of healthcare industry, including pharmaceuticals. (Rosenthal Decl. ¶1.) Dr. Rosenthal was asked by Plaintiffs to "calculate damages equal to the net profits earned by Cephalon on sales of Actiq that were reimbursed by private third-party payors and resulted from the allegedly illegal off-label marketing." (Rosenthal Decl., Executive Summary.) Dr. Rosenthal concluded that "[u]sing the Defendant's own accounting data and standard methods for calculating net profits, [she] ha[s] calculated damages incurred by the Class to be $698.9 million." (Id.)

II. STANDARD OF REVIEW

Federal Rule of Evidence 702 governs the admissibility of expert testimony. Rule 702 provides are follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702 (2011). The Third Circuit has explained that Rule 702 has "three major requirements": the proffered witness must (1) "be an expert, i.e. must be qualified"; (2) "testify about matters requiring scientific, technical[,] or specialized knowledge"; and (3) present testimony that "assist[s] the trier of fact." Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008). Thus, in order to be admitted, an expert's testimony must demonstrate "qualification, reliability, and fit." Schneider ex. Rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir.2003.) "The party offering the expert must prove each of these requirements by a preponderance of the evidence." Mahmood v. Narciso, 549 F. App'x 99, 102 (3d Cir. 2013) (citing In re TMI Litig., 193 F.3d 613, 663 (3d Cir. 1999)).

Rule 702 has "a liberal policy of admissibility." Pineda, 520 F.3d at 243 (quoting Kannankeril v. Terminix Inter., Inc., 128 F.3d 802, 806 (3d Cir.1997)). As such, the "rejection of expert testimony is the exception and not the rule." Fed. R. Evid. 702 advisory committee's

notes. In the seminal case Daubert v. Merrell Dow Pharm., the Supreme Court explained that, under the Federal Rules of Evidence, the trial judge acts as a "gatekeeper" to ensure that "any and all expert testimony or evidence is not only relevant, but also reliable." 509 U.S. at 589; see also Pineda, 520 F.3d at 244; Czarnecki v. Home Depot USA, Inc., CIV.A.07-4384, 2009 WL 1706582 (E.D. Pa. June 15, 2009). "[An] expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." Pineda, 520 F.3d at 244 (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (3d Cir. 1994)). Accordingly, the focus of the Court's inquiry is on the methodology used by the expert, not the conclusions reached. See id. Exclusion of expert testimony is the exception rather than the rule because "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Fed. R. Evid. 702 advisory committee's notes (citing Daubert, 509 U.S. at 595).

III. DISCUSSION

In the present matter, Cephalon contends Dr. Rosenthal's expert report fails each of the Rule 702 requirements, and thus her declaration and testimony must be excluded. Plaintiffs, however, contend that each of Cephalon's arguments go to the weight of Dr. Rosenthal's opinion, but not the admissibility of her testimony. The Court will examine each of Cephalon's arguments in turn.

A. Qualification

"Qualification requires the witness possess specialized expertise," Pineda, 520 F.3d at 244 (citing Schneider, 320 F.3d at 404), which encompasses a "broad range of knowledge, skills, and training," Pineda, 520 F.3d at 244 (citing In re Paoli, 35 F.3d at 741). The Third Circuit

"ha[s] interpreted Rule 702's qualification requirement liberally." Id. (citing Schneider, 320 F.3d at 404 and In re Paoli, 35 F.3d at 741.) Additionally, the Third Circuit has made clear that a witness may be qualified based solely on practical experience. In re Paoli, 35 F.3d at 741 ("Rule 702's liberal policy of admissibility extends to the substantive as well as the formal qualification of experts.") Formal qualifications, such as a degree in a particular field, are therefore not required.

Cephalon first asserts that Dr. Rosenthal is not qualified to offer expert testimony in this case because she is not an expert in cost accounting. In particular, Cephalon emphasizes the conclusions reached by its expert, Christine Hammer, CPA. Hammer was retained by Cephalon to discuss widely accepted methodologies for calculating product profitability in the context of profit disgorgement, and review the data and methodology utilized by Dr. Rosenthal to calculate damages. (Hammer Rpt. ¶13.) According to Cephalon and Hammer, cost accounting provides the analytical framework necessary to understand which costs should be included in a product profitability calculation. Hammer further claims that cost accounting principles are widely accepted by corporations and the federal government as the correct framework for determining the costs and profitability of a product. Thus, Cephalon and Hammer contend that cost accounting is necessary because Plaintiffs seek a profit disgorgement remedy with respect to particular Actiq prescriptions, which requires a determination of product-level profits for Actiq. (See id. ¶¶17, 20-24.)

The Court finds that Cephalon and Hammer's arguments here are based on the unsupported assumption that only an accountant with specific expertise in cost accounting has the necessary expertise to testify regarding economic loss. Dr. Rosenthal is not an accountant,

and she concedes that she has no specialized knowledge, training, or expertise in cost accounting. (Rosenthal Dep. 13:3-20, 149:4-17.) It is equally true, however, that Dr. Rosenthal makes no pretense that she used cost accounting concepts and practices when performing her profit disgorgement analysis.[1] It may be, as Cephalon argues, that an accountant such as Hammer would be better qualified to offer opinion testimony regarding damages because Dr. Rosenthal's approach fails to take into account certain costs when calculating Cephalon's alleged profits. (See Hammer Rpt. ¶¶37-41.) This, however, does not render Dr. Rosenthal unqualified to offer her opinion. The Court need not find that Dr. Rosenthal is the best qualified in a particular specialization for it to be appropriate to admit her testimony. Rather, Dr. Rosenthal's lack of specialization in cost accounting merely goes to the weight of her opinion, not its admissibility. See Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 782 (3d Cir. 1996) ("Because of our liberal approach to admitting expert testimony, most arguments about an expert's qualifications relate more to the weight to be given the expert's testimony than to its admissibility. Thus, witnesses may be competent to testify as experts even though they may not, in the court's eyes, be the 'best' qualified. Who is 'best' qualified is a matter of weight upon which reasonable jurors may disagree."); Cary Oil Co., Inc. v. MG Ref. & Mktg., Inc., 99 CIV.

[1] Dr. Rosenthal explains she calculated damages from an economist's point of view. Specifically, Dr. Rosenthal testified as follows:

> Q. Do you think it's appropriate for a cost accountant to allocate indirect costs to a product for purposes of developing a P and L [profit and loss statement]?
>
> A. Well, let me start by saying I'm not a cost accountant and I'm not opining on what might be appropriate for a cost accountant. *For an economist* when we discuss the profits associated with a product, to me that means the revenues associated with that product less costs that would specifically go away if the product went away.

(Rosenthal Dep. 192:12-23) (objections omitted) (emphasis added).

1725 (VM), 2003 WL 1878246, at *3 (S.D.N.Y. Apr. 11, 2003) (admitting expert witness's testimony, because "[t]he fact that a witness's qualifications are not unassailable does not mean the witness is incompetent to testify; [r]ather it is ... for the jury, with the assistance of vigorous cross examination, to measure the worth of the opinion[s]") (internal citation omitted) (alteration in original); Loeffel Steel Products, Inc. v. Delta Brands, Inc., 387 F. Supp. 2d 794, 802 (N.D. Ill. 2005) ("No case of which we are aware remotely suggests, let alone holds, that only a certified public accountant has the necessary expertise to testify about economic loss. In fact, being a certified public accountant does not ensure admissibility of testimony.")

Dr. Rosenthal has analyzed pharmaceutical manufacturer transactional data and provided expert testimony in more than twenty cases. In particular, she has testified in litigation concerning allegations of improper marketing of the following prescription drugs: Bextra, Lupron, Neurontin, Risperdal, Rituxan, Vioxx, Zyrexa, and Premarin. (Rosenthal Decl. ¶2.) It is therefore evident that Dr. Rosenthal has significant experience in analyzing how pharmaceutical manufacturers calculate product-specific profits. See In re Neurontin Mktg. & Sales Practices Litig., 712 F.3d 21, 42 (1st Cir. 2013) cert. denied, 134 S. Ct. 786, 187 L. Ed. 2d 594 (U.S. 2013) ("It is clear that Dr. Rosenthal's evidence met several requirements of Federal Rule of Evidence 702. Dr. Rosenthal is a witness with the requisite "knowledge, skill, experience, training, or education," Fed.R.Evid. 702, and her opinion would assist the trier of fact to understand the evidence or to determine a fact in issue, Fed.R.Evid. 702(a).")

Accordingly, the Court finds that Dr. Rosenthal is qualified to offer her expert opinion regarding Plaintiffs' alleged damages in this case.

B. Reliability

The Third Circuit has interpreted the reliability requirement "to mean that 'an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.'" Pineda, 520 F.3d at 244 (quoting In re Paoli, 35 F.3d at 742). Additionally, the expert's principles and methods must be reliably applied to the facts of the case. In re Paoli, 35 F.3d at 745; Fed. R. Evid. 702 advisory committee's notes. Importantly, "[w]hile a litigant has to make more than a prima facie showing that his expert's methodology is reliable ... '[t]he evidentiary requirement of reliability is lower than the merits standard of correctness.'" Pineda, 520 F.3d at 247 (quoting In re Paoli, 35 F.3d at 744). The Third Circuit has recognized at least eight factors that a court may consider in assessing whether a particular methodology is reliable: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. Id. at 247–48 (citing In re Paoli, 35 F.3d at 742 n.8). These factors "are neither exhaustive nor applicable in every case." Kannakeril, 128 F.3d at 806–07; see also United States v. Davis, 397 F.3d 173, 178 (3d Cir. 2005). "The District Court has broad discretion in determining the admissibility of evidence, and 'considerable leeway' in determining the reliability of particular expert testimony under Daubert." Simmons v. Ford Motor Co., 132 Fed.Appx. 950, 952 (3d Cir. 2005) (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152–53 (1999)).

Additionally, "the reliability analysis [required by Daubert] applies to all aspects of an experts testimony: the methodology, the facts underlying the expert's opinion, [and] the link between the facts and the conclusion." Heller v. Shaw Indus., Inc., 167 F.3d 146, 155 (3d Cir.1999). In In re Paoli, the Third Circuit clarified that "if a court finds that an expert has employed a methodology only slightly different from a methodology that the court thinks is clearly reliable, the court should be more likely to accept the altered methodology than if it was evaluating that methodology as an original matter." In re Paoli, 35 F.3d at 745 n.14. A judge should only exclude evidence if the flaw is large enough that the expert lacks "good grounds for his or her conclusions." Id. at 746. Further, the proponent of the evidence does not have to demonstrate that the assessments of the expert are correct — they only have to demonstrate by a preponderance of the evidence that their opinions are reliable. Id. at 744. "'The analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination.'" Oddi v. Ford Motor Co., 234 F.3d 136, 146 (3d Cir.2000) (quoting Kannankeril, 128 F.3d at 806).

Here, generally speaking there are roughly five steps in Dr. Rosenthal's damages analysis. Dr. Rosenthal first calculated gross product sales for Actiq for each year of the Proposed Class Period (Step 1). Dr. Rosenthal then deducted product-specific costs, including discounts and rebates, costs of goods sold, marketing expenditures, field sales costs, scientific communications (such as continuing medical education, investigator sponsored trials, and publications), clinical trials and regulatory costs, and miscellaneous other costs (Step 2). Next Dr. Rosenthal calculated the net profits attributable to TPPs for each year of the Proposed Class Period (Step 3). Dr. Rosenthal then calculated the percentage off-label prescriptions using "gold

standard" IMS Health National Disease and Therapeutic Index ("NDTI") data (Step 4). Having calculated the percentage of off-label prescriptions, Dr. Rosenthal then subtracted 15% (Step 5). This 15% figure is from the Actiq Risk Management Program ("RMP"), and according to Plaintiffs represents the "allowed for" off-label margin. Thus, of the alleged total amount of off-label prescriptions from which Cephalon derived profits, 15% of this total amount is allegedly not subject to damages. The table below summarizes the results of Dr. Rosenthal's damages calculations.

Actiq Profits Due to Off-Label Marketing
Attributable to the Class of Third Party Payors Less 15%

Year	Damages
2002	$40,165,808
2003	$92,181,366
2004	$125,227,226
2005	$154,204,744
2006	$287,150,432
Total	**$698,929,575**

Cephalon claims Dr. Rosenthal's methodology is not reliable for the following reasons.

1. Dr. Rosenthal's Use of the 2007 Product Contribution Report (Step 1)

Cephalon first argues that Dr. Rosenthal's analysis is not reliable because she began with a flawed starting point: the 2007 Product Contribution Report produced from Cephalon's files during discovery.

A Product Contribution Report "typically reflect[s] a manufacturer's internal decision-making process with respect to which costs related to a particular product, the manufacturer's methodology for allocating costs to a product, and the manufacturer's internal calculation of product-specific incremental profits." (Rosenthal Rebuttal ¶14.) In Step 1 of her analysis, Dr.

Rosenthal used the 2007 Product Contribution Report "as a general guide for the line items that would be useful in the calculation of Actiq net profit." (Rosenthal Decl., Attach. C.2 at 1.) Dr. Rosenthal then submitted questions to Cephalon regarding the Product Contribution Report, and received two letter responses from Cephalon. (Id.) Using observations from the Product Contribution Report, raw data from Cephalon's database, and the responses from Cephalon, Dr. Rosenthal arrived at the gross product sales for Actiq for each year of the Proposed Class Period. (Id.)

Cephalon asserts Dr. Rosenthal's use of the 2007 Product Contribution Report is improper because the report is not designed to calculate product-level profitability; the report relates to a period of time after the Proposed Class Period;[2] and Dr. Rosenthal does not know who prepared it, the manner in which it was prepared, or even how it was used. Cephalon is correct in all of these observations. Cephalon, however, ignores several keys facts. As previously stated, the Product Contribution Report was created by someone at Cephalon, and was produced by Cephalon in the course of discovery; it is not something that Dr. Rosenthal herself created. The fact that Cephalon is unable to determine whom at its own company created the document, or for what purpose they did so, is not a reason for faulting Dr. Rosenthal's use of the document in her analysis.

Additionally, because of the uncertain circumstances surrounding the document, it is clear that Dr. Rosenthal took appropriate strides to limit her use of the report. For example, Dr. Rosenthal submitted questions to Cephalon in order to verify line items in the Product

[2] There are, apparently, no Product Contribution Reports prior to 2007. (Rosenthal Decl., Attach. C.2 at 1 n.1.)

Contribution Report and inform her understanding of its contents, and excluded more questionable costs.[3] (See Rosenthal Dep. 165:18-167:3.) Importantly, Cephalon's rebuttal expert, Hammer, does not challenge Dr. Rosenthal's assertion that her use of the Product Contribution Report was relatively conservative.

Further, Dr. Rosenthal's use of the Product Contribution Report was necessitated by the fact that Cephalon "did not systematically produce product-level profit and loss statements — i.e., allocate profits to specific products — during the Class Period." (Rosenthal Decl. ¶11; see also Rosenthal Dep. 156:11-157:16.)[4] According to Hammer the fact that Cephalon did not utilize product level profitability analyses in the ordinary course of business is not unusual. (Hammer Rpt. ¶ 46.) Dr. Rosenthal counters that in her experience over the course of a more

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[3] Specifically, Dr. Rosenthal testified:

> I have used this document merely as a general guide. I examined every Actiq-related account or cost center in the data and evaluated whether and how to include these line items into my profit calculation. Where it was unclear whether a given data element or line should be included in my profit calculation, I have attempted to be conservative by including costs and excluding revenues. If a given undocumented line item was *de minimis* in magnitude (typically less than $1,000 for a given year), I have disregarded such items.

(Rosenthal Decl., Attach. C.2 at 1.)

[4] Specifically, Dr. Rosenthal offered the following explanation for why she used the Product Contribution Report as a starting point for understanding the raw data:

> Because I was told that the company did not produce product profit and loss statements. That's where I [usually] would have started. In other analyses for similar matters when I have been asked to calculate unjust enrichment, I have used company profit and loss statements for their products.

Dr. Rosenthal further elaborated:

> And so [the 2007 Product Contribution Report] at least allowed me to go into [Cephalon's] account system, understand how it was organized, because I could map the totals here to that accounting system…[I]t allowed me to get a first look at, for example, the way the codes in the accounting system assigned costs to a particular product and a particular cost center to understand that logic.

(Rosenthal Dep. 156-11:157:16.)

than a dozen pharmaceutical cases, manufacturers produce profitability statements by product in the regular course of business. (Rosenthal Rebuttal ¶ 14.) Dr. Rosenthal therefore finds it "difficult to understand" why Cephalon "never created any kind of product-level profitability report for Actiq or any other product during the Class period." (Id.) Whichever perspective is correct, the fact remains that Dr. Rosenthal's task of calculating Cephalon's alleged gross product sales from Actiq inherently involves recreating data that Cephalon does not itself contemporaneously keep in the ordinary course of business. Given that Cephalon does not itself keep product-specific information, and that there are no Product Contribution Reports prior to 2007, it is unclear what data other than the 2007 Product Contribution Report Dr. Rosenthal could have used. Notably, there has been no suggestion by Cephalon or Hammer that better data was available.

Under these circumstances, the Court agrees with Plaintiffs that Dr. Rosenthal's use of the 2007 Product Contribution Report was a reasonable starting point for understanding which transactional data related to Actiq. The Court is therefore satisfied that Dr. Rosenthal has articulated "good grounds" for the use of the 2007 Product Contribution Report in her damages analysis. See In re Paoli R.R., 35 F.3d at 742 (the expert must have "good grounds" for his or her opinion) (citing Daubert, 509 U.S. at 590); see also id. at 743 ("[T]he requirement of reliability, or 'good grounds,' extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case.")

2. Costs Not Included in Dr. Rosenthal's Analysis (Step 2)

Cephalon next argues Dr. Rosenthal failed to consider numerous categories of cost in her analysis. In this regard Cephalon again relies on Hammer's expert opinion.

Hammer again emphasizes that cost accounting provides the appropriate analytical framework to understand which costs should be included in a product profitability calculation. Hammer opines that because she understands profit disgorgement to be "a legal concept that varies by state," there can be no single reasonable estimate of Actiq's profitability." (Hammer Rpt. ¶ 10.) Hammer avers that any analysis must first begin by defining the expenses to be properly included given a particular state's standard for profit disgorgement, and only then calculating profits using the relevant expenses. (Id.) Hammer opines that three analytical steps are necessary: (1) identifying the costs associated with all business functions that are needed to produce and sell Actiq in order to estimate the product profitability of Actiq;[5] (2) understanding the fixed and variable costs required to produce and sell Actiq in order to estimate Actiq's profitability over the Proposed Class Period;[6] and (3) understanding how Cephalon's accounting system recorded the direct and indirect costs associated with producing and selling Actiq.[7] (Id. ¶¶28-29.) In sum, Hammer argues that analyzing costs by business function provides the basis for determining which costs should be included given individual state guidelines for profit

[5] According to Hammer, there are six primary business functions that are required to produce and sell a pharmaceutical product: (1) research; (2) development/design; (3) production; (4) marketing; (5) distribution; and (6) customer service (collectively, the "value chain" of the product). (Hammer Rpt. ¶¶29-35.) In addition, each of these business functions requires general and administrative support functions (i.e., corporate governance, regulatory and legal expertise, HR, accounting and finance, IT, employee salaries, facilities costs, training costs, etc.) (Id. ¶ 36.)

[6] According to Hammer variable costs are costs that change in proportion to volume, while fixed costs are those that remain unchanged for a given time period despite wide changes in volume. (Hammer Rpt. ¶¶38-39.) However, according to Hammer, all costs become variable in the long run. (Id. ¶39.) Hammer asserts that she "[has] not yet encountered a business in which a five-year horizon would not be sufficient for the firm to 'change all of its inputs' making most, if not all, of Actiq's costs variable during the Proposed Class Period." (Id.)

[7] Hammer asserts that the costs required to produce and sell a given product can also be direct or indirect, in addition to being fixed or variable. Direct costs are those that can be traced directly to a given product, and include production costs, honorariums for conference speakers, Actiq clinical trials, and Actiq marketing literature. (Hammer Rpt. ¶43.) Indirect costs are those that cannot be traced to a product in an economically feasible way, but which are required to produce and sell a product. (Id.)

disgorgement. This is because it identifies which of those costs can be directly traced and which costs must be allocated to Actiq.

Based on the foregoing, Hammer concludes that Dr. Rosenthal's methodology, in part because it relied on the aforementioned 2007 Product Contribution Report, only considered direct variable costs. Accordingly, Hammer charges that Dr. Rosenthal's methodology for estimating relevant costs is flawed in at least three ways: (1) Dr. Rosenthal has not considered fixed direct costs in her analysis;[8] (2) Dr. Rosenthal has not *fully* considered variable indirect costs in her analysis;[9] and (3) Dr. Rosenthal has not considered fixed indirect costs in her analysis.[10] Hammer opines that a calculation of profits for the purpose of profit disgorgement must take into account the relevant legal guidelines of each individual state. However, Dr. Rosenthal's methodology does not conduct its profitability analysis on a state-by-state basis, and allegedly lacks the flexibility to include or exclude cost components as required by each state. Thus, because Hammer asserts Dr. Rosenthal's analysis fails to take account of cost accounting principles, it is insufficient for determining damages in this matter. (Id. ¶¶50-76.)

[8] These are costs directly related to Actiq that do not fluctuate with volume. Hammer claims Dr. Rosenthal has completely ignored fixed direct costs incurred to produce and sell Actiq. For example, Dr. Rosenthal did not consider both the cost to acquire Actiq as part of Cephalon's $340 million acquisition of Anesta (the company that developed the product) and the costs of acquiring the US Actiq marketing rights from Abbott Laboratories in 2000 ($23.85 million amortized over the subsequent 10 year period). (See Hammer Rpt. ¶¶54-55, 60-65.)

[9] These are costs that relate to more than one product, and do fluctuate with volume. According to Hammer, the only variable indirect cost Dr. Rosenthal considered in her analysis was sales force expenditures. However, Hammer argues Dr. Rosenthal ignored other variable indirect costs such as the costs of R&D, sales and marketing, customer support, and the general and administrative functions supporting each of these business functions. Additionally, Dr. Rosenthal did not consider the tens of millions of dollars that Cephalon spent on programs such as quality assurance and "Drug Safety & Disposition." (See Hammer Rpt. ¶¶54-55, 66-74.)

[10] These are costs that relate to more than one product, and do fluctuate with volume. Hammer claims Dr. Rosenthal has completed ignored fixed indirect costs incurred to produce and sell Actiq. For example, Dr. Rosenthal did not consider millions of dollars in corporate governance costs. (See Hammer Rpt. ¶¶54-55, 75-76.)

Dr. Rosenthal counters by averring that Hammer's criticisms of her methodology are misplaced. Dr. Rosenthal first argues it is inappropriate to include fixed indirect costs in the calculations. Dr. Rosenthal argues a cost accountant may have a standard approach to assessing profitability for public reporting or other purposes, but these standards do not relate to the law and economics concept of profit disgorgement. (Rosenthal Rebuttal ¶7.) It is Dr. Rosenthal's opinion, as an economist, that the calculation of net profits from Actiq sales "is appropriately approached as a problem of incremental profits — the difference between the net revenues earned on these sales and the marginal costs of producing and selling these units." (Id. ¶ 8.) Dr. Rosenthal asserts neither indirect nor fixed costs belong in such a calculation because "by definition neither of these categories of costs directly varies with the number of units. Since these costs are fixed, they would be borne in the actual world and in the but-for world."[11] (Id.) Dr. Rosenthal claims that in order to justify deducting the costs identified by Hammer from the incremental net profit calculation, one would have to create different scenarios in which Cephalon makes different investment or overhead decisions. (Id. ¶10.) However, Dr. Rosenthal argues, this is not the purpose of the economic measure of damages. The purpose of an economic analysis of damages is to accurately measure the increase in profits caused by an allegedly unlawful act. As such, Dr. Rosenthal contends that sunk costs (i.e., fixed costs incurred in the past that are not recoverable) and costs that would have been the same in both the actual world and the but-for world should not be included. (Id.)

Dr. Rosenthal therefore maintains that she has included all direct and indirect product

[11] Dr. Rosenthal further notes the legal concept of disgorgement has conceptual parallels to "but-for" analyses that are common in damages calculations. (Rosenthal Rebuttal ¶9.)

costs that are appropriate.[12] Plaintiffs thus argue that Dr. Rosenthal's calculation of damages provides a reasonable approximation of the amount of wrongful gain, and is therefore consistent with § 51 of the Restatement (Third) of Restitution and Unjust Enrichment.[13] Plaintiffs further argue that the question of whether Dr. Rosenthal should have allocated additional costs to Actiq

[12] For instance, Dr. Rosenthal testified:

> For an economist when we discuss the profits associated with a product, to me that means the revenues associated with that product less costs that would specifically go away if the product went away. And the CEO would still receive a salary. And so those costs are not allocated, and the general counsel would also receive a salary if Actiq suddenly mysteriously 70 percent of it disappeared. So the costs that I've included are those that are truly product-specific.

(Rosenthal Dep. 192:19-194:17.)

[13] Section 51 provides, is relevant part:

> **§ 51 Enrichment by Misconduct; Disgorgement; Accounting**
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> ***
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> (4) Unless the rule of subsection (2) imposes a greater liability, the unjust enrichment of a conscious wrongdoer, or of a defaulting fiduciary without regard to notice or fault, is the net profit attributable to the underlying wrong. The object of restitution in such cases is to eliminate profit from wrongdoing while avoiding, so far as possible, the imposition of a penalty. Restitution remedies that pursue this object are often called "disgorgement" or "accounting."
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> (5) In determining net profit the court may apply such tests of causation and remoteness, may make such apportionments, may recognize such credits or deductions, and may assign such evidentiary burdens, as reason and fairness dictate, consistent with the object of restitution as specified in subsection (4). The following rules apply unless modified to meet the circumstances of a particular case:
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> > ***
> > (d) A claimant who seeks disgorgement of profit has the burden of producing evidence permitting at least a reasonable approximation of the amount of the wrongful gain. Residual risk of uncertainty in calculating net profit is assigned to the defendant.

Restatement (Third) of Restitution and Unjust Enrichment § 51 (2011).

is a question for the jury, not a basis on which to disqualify her opinion as unreliable. Similarly, Plaintiffs maintain that the question of whether Dr. Rosenthal failed to consider certain categories of cost is an issue that does to the weight of her opinion, not to admissibility.

The Court agrees with Plaintiffs. The Court again notes that that Hammer's criticisms of Dr. Rosenthal's methodology rest on the erroneous assumption that cost accounting is the only appropriate measure for determining damages in this matter. The Court, however, finds that the issue of whether certain costs should have been included in Dr. Rosenthal's analysis is ultimately more a question of the accuracy of her analysis, not necessarily the methodology she used in conducting her analysis. Underscoring such potential inaccuracies is the purpose of cross-examination.

Further, as the foregoing discussion demonstrates, Hammer's critiques of Dr. Rosenthal's analysis primarily represent a difference of opinion. Hammer, speaking from the arguably more exacting point of view of cost accounting, essentially argues that Dr. Rosenthal's analysis fails to include certain categories of costs, and therefore is an inaccurate representation of Actiq's profitability. Dr. Rosenthal, speaking from the arguably more general point of view of an economist, outlines her reasons for concluding that inclusion of many of these costs is inappropriate. Which of these opinions is a more accurate reflection of Cephalon's profits, and therefore Plaintiffs' alleged damages, is a question for the jury. Cf. Kansas Gas & Elec. Co. v. United States, 95 Fed. Cl. 257, 308 (Fed. Cl. 2010) aff'd in part, rev'd in part, 685 F.3d 1361 (Fed. Cir. 2012) ("what makes for good business accounting does not translate automatically into a fair and reasonable apportionment of damages.") It is not a ground for excluding Dr. Rosenthal's declaration and testimony in its entirety.

3. Dr. Rosenthal's Use of NDTI Data (Step 4)

Cephalon next argues that Dr. Rosenthal's methodology for determining the percentage of off-label prescriptions written during each year of the Proposed Class Period is unreliable because it relies on IMS Health National Disease and Therapeutic Index ("NDTI") data. NDTI collects data on the disease and treatment patterns faced by office-based private practice physicians in the United States. (Bradford Rpt. ¶106.) The survey captures "drug appearances" (i.e., prescriptions), along with the specialty of the surveyed physician and detailed diagnostic information. (Id.) The IMS generates national estimates for drug prescriptions by weighing the sample data based on physician specialty and geographic location. (Id.) According to David Bradford, Ph.D,[14] Cephalon's expert, Dr. Rosenthal utilizes NDTI national estimates for Actiq prescriptions along with physician specialty and diagnosis data in her damages calculations in the following manner: Dr. Rosenthal classifies diagnoses as on-label or off-label based on the ICD-9 diagnostic codes and calculates the alleged off-label prescriptions as a percentage of the national estimates. (Id. ¶107.) Dr. Rosenthal herself states:

> The IMS NDTI data contain ICD-9 codes that describe the indication for which Actiq was prescribed. I have designated all ICD-9 codes related to cancer as on-label, and all remaining codes have been designated as off-label.

(Rosenthal Decl. ¶ 15.) Cephalon concedes that NDTI data "may be reliable for certain purposes, particularly in providing estimates with respect to widely-prescribed drugs," but nonetheless claims that the data is "*wholly unreliable* for Rosenthal's purposes here." (Def.'s

[14] Dr. Bradford is the Chair of Public Policy and a Professor in the Department of Public Administration and Policy at the University of Georgia. He has 20 years of research experience in the area of health economics, which include the study of the health insurance sector. For the past ten years, Bradford has also researched how pharmaceutical advertising affects patients and physicians.

Mot. Exclude 15) (emphasis added). Cephalon contends the NDTI data is flawed for at least three reasons.

a. Small Sample Size

First, Cephalon claims the NDTI data's sample size is too small, and therefore is unreliable for estimating the amount of prescriptions that were off-label for Actiq for any given year. Dr. Bradford states the total number of Actiq prescriptions in the NDTI sample across the entire Proposed Class Period (2002-2006) is 82. (Bradford Rpt. ¶109.) This small sample forms the basis for Dr. Rosenthal estimating national Actiq prescriptions to be 202,489 for the Proposed Class Period. (Id. ¶110.) National Actiq prescriptions are estimated for each of the five years using annual samples ranging in size from 6 to 30 prescriptions. (Id. ¶¶109.) The average annual sample size from 2002 to 2006 is 16.4 prescriptions. (Id. ¶110.) Bradford argues that from a statistical standpoint, the small sample size is problematic because it results in unreliable national estimates of Actiq off-label prescriptions. (Id. ¶111.) For her part, Dr. Rosenthal concedes that that the sample size is small. (Rosenthal Rebuttal ¶21; Rosenthal Dep. 255-19-256:2; 263:19-265:16.) Nonetheless, Dr. Rosenthal maintains there is no reason to expect bias in her results (i.e., random errors around the estimates of off-label use). Dr. Rosenthal also points out that any random errors in measuring off-label use would be less when considered over the whole Proposed Class Period, because annual errors will tend to offset one another. (Rosenthal Rebuttal ¶21.)

The Court declines to disregard Dr. Rosenthal testimony based on her use of the NDTI due to its small sample size. Whatever its empirical deficiencies, NDTI data is generally accepted as the academic, government, and industry standard for the estimation of the number of

prescriptions linked to specific diagnoses in the United States. (See Rosenthal Rebuttal ¶¶18) ("NDTI data are the gold standard for the estimation of national prescription medication use linked to specific diagnoses and related to promotional activities in academic, government and industry research and forecasting. The methods employed to present this information in my Declaration are standard practice in the relevant peer reviewed literature."). Indeed, as Plaintiffs point out, Dr. Bradford in his own research has published studies based in IMS data. (See Pls.' Resp. Opp'n 22 n. 44.) Still further, other courts have recognized IMS data to be the "gold standard" for purposes of calculating damages on behalf of TPPs. See e.g., New England Carpenters Health Benefits Fund v. First DataBank, Inc., 248 F.R.D. 363, 370 (D. Mass. 2008); In re Neurontin Mktg. & Sale Practices Litig., 244 F.R.D. 89 (D. Mass. 2007); In re Cardizem CD Antitrust Litig., 218 F.R.D. 508, 526 (E.D.Mich.2003) (holding, for settlement purposes, the Plaintiffs used IMS data to "make an informed judgment of ... the potential damages arising" from the alleged antitrust violation).

Additionally, of particular relevance to this case, Actiq's Risk Management Program ("RMP") specifically states that NDTI data is to be used to monitor Actiq's prescription and use. Section 8.2.2 of the RMP provides: "National prescription data segmented by physician specialty and by indication from the IMS National Disease and Therapeutic Index (NDTI) will be analyzed." (Pls.' Proffer of Facts, Ex. 4, § 8.2.2 at 23.) The RMP also went so far as to attach an example of an NDTI data sheet to the RMP. (Id.) Thus, Plaintiffs rightly argue that the FDA was clear that the monitoring of prescriptions of Actiq should occur through examination of NDTI

data.[15] For this reason, it was reasonable for Dr. Rosenthal to use the same NDTI data to calculate the percentage of off-label use for purposes of damages.

b. Specialties Excluded

Second, Cephalon contends another flaw in Dr. Rosenthal's reliance on the NDTI data is the fact that the survey did not include physicians from all medical specialties who prescribed Actiq during the Proposed Class Period. Dr. Bradford concludes the NDTI estimates for Actiq prescriptions are based on a sample that is not representative of the entire population of physicians prescribing Actiq. (Bradford Rpt. ¶114.) Instead, the NDTI survey only includes physicians from all primary care specialties involved in direct patient care. (Id.) This means, for example, that anesthesiologists are not included in the survey. Dr. Bradford argues this is a considerable flaw because "anesthesiologists/pain specialists" wrote a large proportion of Actiq

[15] Additionally, Plaintiffs point out that in order to obtain the FDA's approval of Actiq, the original manufacturer of Actiq provided assurances to the FDA's Center for Drug Evaluation and Research Anesthetic and Life Support Drugs Advisory Committee regarding how the NDTI data would be used. For example, the manufacturer testified:

> I mentioned this morning that we were going to be doing an ongoing monitoring of different surveillance programs out there, and…NDTI…will give us information, as I said, on a quarterly basis as to who's prescribing the drug for what indication. And you can check very easily there and see whether the oncologists are prescribing Actiq™ or whether dermatologists—terrible thought—would be prescribing Actiq™. So that will give us an indication of whether or not it's being used appropriately.

(Pls.' Rebuttal Proffer of Facts ¶¶15-16) (Transcript of Meeting before the Food and Drug Administration's Center for Drug Evaluation and Research Anesthetic and Life Support Drugs Advisory Committee, Sept. 17, 1997, at 196.) The manufacturer further testified before the FDA that it would use the NDTI data to analyze whether Actiq was being prescribed on- or off-label.

> We have what we call a quality assurance program which is really our vigilance program, and how we're going to monitor how this drug is used. There are a variety of surveillance programs that we will be using, including national databases such as the NDTI and the NPRA which are programs that routinely track how drugs are being prescribed, who's prescribing them, what the diagnosis is.

(Id. at 100.)

prescriptions during the Proposed Class Period. (Id.) Dr. Bradford further argues that, because the survey only includes office-based private practice physicians, Dr. Rosenthal's conclusions about the overall off-label Actiq prescriptions could be different to the extent that physicians in other settings such as non-private clinics or hospitals have different on- and off-label prescribing patterns. (Id. ¶115.) Likewise another of Cephalon's experts, Dr. Michael Ashburn,[16] notes that neither pain specialists nor hospice and palliative medicine specialists are included in the NDTI data. (Ashburn Rpt. ¶ 47.) Cephalon concludes these limitations in the NDTI data are significant because "anesthesiologists/pain specialists wrote over half of all Actiq prescriptions during the Class Period"; thus, their exclusion means that the "prescribing trends of critical physician groups is simply not reflected in the NDTI data and Rosenthal has no way of knowing whether their level of off-label prescribing was higher, lower, or the same as the handful of doctors who did participate in the NDTI survey and reported prescribing Actiq." (Def.'s Mot. Exclude 18.)

Dr. Rosenthal acknowledged at her deposition that anesthesiologists are not included in the survey, (Rosenthal Dep. 213:10-22; 218:14-16), and that she did not know whether pain specialists were included, (id. 214:15-23.) Dr. Rosenthal rebuts Drs. Bradford and Ashburn's criticism, however, by asserting that the fact that NDTI does not include anesthesiologists or pain specialists is not something that can be addressed empirically because of the absence of data. (Rosenthal Rebuttal ¶22.) Dr. Rosenthal also points out that Actiq was specifically approved for breakthrough cancer pain, while anesthesiologists, pain specialists, and palliative medicine

[16] Dr. Ashburn is a professor in the Department of Anesthesiology and Critical Care at the University of Pennsylvania Perelman School of Medicine. He is also a senior fellow at University of Pennsylvania, Leonard Davis Institute of Health Economics. Dr. Ashburn is a pain management and palliative care physician, and his clinical practice is dedicated to the diagnosis and treatment of pain.

specialists have a broader scope of practice. (Id.) Thus, in theory, these generalists (and any other physician category outside of oncology) would tend to increase the percentage of off-label use, not decrease it as Dr. Bradford seems to suggest. (Id.)

Based on the arguments presented, the Court will not exclude Dr. Rosenthal's declaration and testimony simply because the NDTI data she relied on does not include physicians from certain medical specialties. As with Cephalon's argument that certain costs should have been included in Dr. Rosenthal's analysis, the Court likewise finds that the issue of whether certain specialties should (or could) have been included in Dr. Rosenthal's calculation is ultimately more a question of the accuracy of her analysis, not the methodology she used in conducting her analysis. The Court would also again observe that there has been no suggestion by Cephalon or Drs. Bradford and Ashburn that better data in available. Further, whether the inclusion or exclusion of these specialties would increase (as Dr. Bradford suggests) or decrease (as Dr. Rosenthal suggests) the percentage of off-label prescribing remains an open question that can only be resolved by the jury. It is not a ground for excluding Dr. Rosenthal's testimony in its entirety.

c. IMS Coding

Finally, Cephalon claims there are significant limitations in the IMS coding system. Dr. Bradford asserts that Dr. Rosenthal's classification of the diagnoses in the NDTI data as on- and off-label is both inconsistent and inaccurate. Dr. Bradford states that many diagnosis codes in the NDTI data are not obviously related or unrelated to cancer, especially to a layperson such as Dr. Rosenthal. (Bradford Rpt. ¶116.) Dr. Bradford claims that correcting for inconsistencies reduces the percentage of off-label prescriptions in 2003 from 87.5% to 72%, and in 2005 from

80.9% to 70.5%. (Id.) Dr. Bradford further points out that the NDTI only records one diagnosis for one drug prescription. (Id. ¶117.) However, in reality, a physician may have several diagnoses for a particular patient related to various symptoms and conditions, a fact acknowledged by Dr. Rosenthal. (Id.) (citing Rosenthal Dep. 256:15-257:13.) This possibility of coding for a symptom rather than the cause of pain is also confirmed by Dr. Deborah Leiderman,[17] Plaintiffs' regulatory expert, in her deposition. (Id.) (citing Leiderman Dep. 281:9-18.)

Likewise, Dr. Ashburn also opines that it is impossible for Dr. Rosenthal to make a determination of whether off-label prescriptions were inappropriate based solely on examining the IMS NDTI data and the ICD-9 coding. (Ashburn Rpt. ¶43.) Dr. Ashburn claims this is because the ICD-9 coding is not a reliable indicator of the reasons for a prescription. (Id. ¶45.) As a result, Dr. Ashburn concludes, only careful review of the individual patient's medical records can lead to a proper determination of whether the use of Actiq was medically necessary. (Id.) Finally, Dr. Ashburn again asserts the NDTI data used by Dr. Rosenthal may have excluded pain specialists, and these specialists need to be included in the assessment. (Id. ¶46.)

Both Dr. Rosenthal and Dr. Leiderman agree there are problems inherent in the ICD-9 coding. (See Rosenthal Dep. 244:19-21; Leiderman Dep. 282:7-283:10.) As such, Dr. Rosenthal concedes it is possible that a true on-label use would appear to be off-label. (Rosenthal Rebuttal

[17] Dr. Leiderman is a Board Certified Neurologist and Fellow at the American Academy of Neurology. Dr. Leiderman has extensive experience in pharmacology, clinical trials, the development of medications that affect the brain or central nervous system, and in drug regulation. Dr. Leiderman conducted and directed clinical trials within the pharmaceutical industry for three years and at the National Institutes of Health for ten years prior to joining the FDA Center for Drugs (CDER) for seven and a half years. Dr. Leiderman served as Director of the Controlled Substance Staff at FDA CDER from 2000 to 2007.

¶23.) However, Dr. Rosenthal again maintains that this data is the best available data for identifying specific uses of prescription drugs. (Id.) Dr. Rosenthal also argues that her methodology has assumed that all cancer-related pain indications are on-label, even though Actiq is only approved for breakthrough cancer pain. (Id.) As such, Rosenthal maintains her calculations are conservative. (Id.; see also Rosenthal Dep. 249:10-21.)

For the reasons previously outlined, the Court again declines to exclude Dr. Rosenthal's declaration based on admitted deficiencies in the IMS coding. It simply defies reason for Cephalon to suggest that data which was deemed reliable for purposes of monitoring off-label prescriptions when Actiq was approved by the FDA is somehow "wholly unreliable" in estimating the percentage of off-label prescriptions for purposes of calculating damages. There again has been no suggestion by Cephalon or its experts that better data is available. Beyond this, Dr. Ashburn's suggestion that every patient file should be reviewed individually presents obvious practical difficulties which the Court need not address.

4. Dr. Rosenthal's "Causation Assumption" (Step 5)

Cephalon next contends that Dr. Rosenthal's methodology is unreliable because Dr. Rosenthal impermissibly accepted Class counsel's assumption that all off-label prescriptions in excess of 15% "resulted from the allegedly illegal off-label marketing." (Def.'s Mot. Exclude 11) (quoting Rosenthal Decl., Executive Summary); (see also Rosenthal Dec. ¶14) ("Counsel has advised me that they are seeking damages in the form of profits only for the portion of sales relating to the allegedly fraudulent off-label marketing of Actiq. On-label prescriptions of Actiq are not subject to damages. Furthermore, I have been asked to assume that all off-label uses of Actiq in excess of 15% of total prescriptions are subject to damages.") Dr. Rosenthal's

presumption that "all off-label uses of Actiq in excess of 15% of total prescriptions are subject to damages" is centered on the FDA's Actiq Risk Management Program ("RMP"), which was adopted when Actiq was first approved by the FDA in 1998. (Rosenthal Decl. ¶14.) Specifically, Section 9.1.2. of the Actiq RMP reads as follows:

> If groups of physicians (such as a particular specialty) are identified as having prescribed Actiq inappropriately, and these prescriptions represent potential off-label usage greater than 15% of total quarterly Actiq prescriptions, Abbott will contact the appropriate professional society (i.e. American College of Surgeons, American Society of Anesthesiologists). This letter will outline concerns and offer to implement an educational program in conjunction with the professional society in a national setting.
>
> Prescribing patterns will be monitored for the physician groups in question and should the level continue to exceed 15% of total Actiq prescriptions for 2 additional quarters, an aggressive educational program will be initiated by mail clearly warning of the potential liabilities of prescribing Actiq to inappropriate patient populations.

(Pls.' Proffer of Facts, Ex. 4, at 26-27.) Dr. Rosenthal avers that the Actiq RMP embodies a presumption "that there is a positive level of off-label prescribing that can result from clinical judgment by physicians, but this level of prescribing would not exceed 15% of total quarterly Actiq prescriptions absent the alleged misconduct." (Rosenthal Decl. ¶14.)

Dr. Leiderman explains that RMPs (also known as RiskMAPS) were developed by FDA for selected drug products that demonstrated patient benefit while also posing significant risk. (Leiderman Decl. ¶12.) According to Dr. Leiderman an RMP is, essentially, "a safety program designed to meet specific objectives in minimizing product risks while preserving the benefits." (Id.); (see also Gottlieb Rpt. ¶¶37-38) (defining an RMP as a "strategic safety program" designed to minimize the known risks of a product and preserve its benefits.) In order to balance product risk and patient safety, RMPs "may incorporate a range of programs and tools such as registries,

education programs for prescribers and/or patients, etc. that extend beyond the routine drug product label or package insert to support safe use." (Leiderman Decl. ¶12.) According to Dr. Leiderman, Actiq was the first analgesic opioid approved with a RMP and with restrictions to ensure safe use. (Id. ¶13.) In 1998, FDA explicitly approved Actiq only for breakthrough pain associated cancer. Dr. Leiderman avers FDA CDER's Division of Analgesic Products specifically approved Actiq under 21 CFR 314.520 (Subpart H), a special provision reserved for drug products that meet unmet medical need but have significant safety risks. (Id.) From this, Dr. Leiderman concludes:

> In its decision to approve Actiq under the Subpart H regulations with restrictions on the use of Actiq, and with the requirement for extensive ongoing monitoring and reporting of prescribing patterns to the FDA — well beyond routine safety and reporting requirements — FDA was using its full authority to limit the use of Actiq to the intended, cancer pain population.

(Id. ¶ 16.) Dr. Leiderman further opines that "FDA would not have approved the drug Actiq containing the high potency narcotic fentanyl, historically used for analgesia in hospitals, for use at home by patients, except for the pressing need for relief of severe cancer pain not adequately controlled by other narcotic therapy." (Id. ¶ 21.) Dr. Leiderman also notes that FDA required Anesta (the company that, along with Abbott Laboratories, developed Actiq) to monitor and report prescribing patterns by indication and specialty of prescriber as a component of the RMP at the time of approval. (Id. ¶22.) Dr. Leiderman's asserts that this detailed reporting has been required for very few products, and that these additional requirements attest to the FDA's seriousness about compliance with the labeled indication. (Id. ¶¶22-23.)

Cephalon, however, contends that Dr. Rosenthal's assumption of a 15% threshold is both arbitrary and inconsistent with Dr. Rosenthal's academic work. For instance, Cephalon points

out that Dr. Rosenthal admitted she did not know how the 15% was derived (see Rosenthal Dep. 82:8-21), and that Dr. Leiderman herself described the 15% trigger as "pretty arbitrary." (Leiderman Dep. 270:10-18.) Cephalon's experts, meanwhile, opine that there is no causal link between off-label promotion and the 15% threshold articulated in the RMP. Dr. Scott Gottlieb,[18] Cephalon's regulatory expert, opines that because RMPs are not intended to regulate the practice of medicine, they do not explicitly limit the off-label use of drugs or dictate when a drug is medically appropriate for a given patient. Dr. Gottlieb claims that since determination of a product's safety is an individualized assessment and the FDA does not regulate the practice of medicine, RMPs are not intended to limit or provide a bright line rule for when a physician may prescribe a medicine off-label. Partly for this reason, Dr. Gottlieb concludes that Plaintiffs misinterpret the Actiq RMP. Dr. Gottlieb avers that Dr. Leiderman's conclusion that through the Actiq RMP FDA "was using its full authority to limit the use of Actiq to the intended, cancer pain population" is incorrect. (Gottlieb Rpt. ¶ 45.) Dr. Gottlieb counters Dr. Leiderman's opinion by stating that the Actiq RMP did not prevent or restrict physicians from exercising their independent medical judgment when prescribing Actiq. (Id. 45.) The Actiq RMP also did not control access to Actiq for off-label purposes. (Id. ¶46.) Further, the FDA, through the Actiq RMP did not attempt to use all the tools it could have to influence physicians to prescribe Actiq on-label. (Id.) Instead, the Actiq RMP only required the sponsor to implement an education program if the percentage of off- label prescriptions exceeded 15% of quarterly Actiq

[18] From 2003-2004, Dr. Gottlieb was first a Senior Advisor to the FDA Commissioner and then served as FDA's Director of Medical Policy Development. After leaving the FDA in 2004, Gottlieb returned from 2005-2007 to serve as FDA Deputy Commissioner for Medical and Scientific Affairs by appointment of President George W. Bush. Gottlieb is currently an attending physician at NYU's Tisch Hospital and a Clinical Assistant Professor at the NYU School of Medicine. Gottlieb is also a Resident Fellow at the American Enterprise Institute.

prescriptions. (Id. ¶47.) The purpose of the education program was to ensure that the physicians could be properly informed of Actiq's potential risks for "opioid non-tolerant patients" — i.e., patients who were considered to be naïve about opioid therapy. (Id. ¶49.) Dr. Gottlieb further opines that by addressing the off- label usage, the Actiq RMP "contemplated that off-label prescribing of Actiq would occur." (Id. ¶ 51.) However, Dr. Gottlieb asserts there is simply no link between the 15% threshold in the Actiq RMP and the off-label promotion.

Similarly, Cephalon's marketing expert, Pradeep Chintagunta,[19] also asserts that Dr. Rosenthal's reliance on the RMP is flawed for two reasons. First, Chintagunta notes that the language of the Actiq RMP does not support Dr. Rosenthal's conclusions. For instance Section 9.1.1 of the RMP states that if "groups of physicians (such as a particular specialty) are identified as having prescribed Actiq inappropriately, and these prescriptions represent potential off-label usage greater than 15% of total quarterly Actiq prescriptions," then Cephalon must undertake certain educational efforts. (Chintagunta Rpt. ¶30.) Chintagunta states that, despite Dr. Rosenthal's assertions to the contrary, the Actiq RMP does not state that off-label marketing is the *cause* of off-label prescriptions. Chintagunta asserts the RMP makes no observations as to why physicians might prescribe Actiq for off-label indications. (Id. ¶31.) Indeed, Chintagunta notes, Dr. Leiderman testified (1) that the FDA did not have the authority to dictate to practitioners that they could only prescribe drugs for indications on the label, and (2) no link exists between off-label promotion and the 15% threshold. (Id.)

Second, Chintagunta asserts that Dr. Rosenthal's own academic research, which uses econometric methods, has concluded that many factors other than promotions affect drug sales

[19] Pradeep Chintagunta is a Professor of Marketing at the University of Chicago Booth School of Business.

and the likelihood that patients are prescribed a particular drug. (Id. ¶34.) These factors include the type of health plan, the availability of co-insurance, physician specialty, patient gender, and the region where the patient lives.[20] (Id. ¶35.) Similarly, Cephalon argues that Dr. Rosenthal's causation assumption is inconsistent with her analysis in other cases involving alleged off-label promotion. In these cases, Cephalon contends Dr. Rosenthal has used regression analysis to try to establish causation. (Rosenthal Dep. 75:9-19.) Dr. Rosenthal has further testified that regression analysis is the "standard approach" for economists. (Id. 77:1-11.) However, by her own admission, Dr. Rosenthal has not used that "standard approach" in this matter. (Id. 79:18-20.)

The Court finds that Cephalon and its experts have identified numerous deficiencies with Dr. Rosenthal's causation assumption. Plaintiffs broadly aver that Daubert permits damages experts to assume causation. (Pls.' Resp. Opp'n 16-17). While this is generally true, Cephalon has correctly noted that while experts are permitted to rely on assumptions, to be admissible the assumption must be based on sound methodology. See In re TMI Litig., 193 F.3d 613, 677 (3d Cir. 1999) amended, 199 F.3d 158 (3d Cir. 2000) ("Although Daubert/Paoli analysis does not preclude testimony merely because it may be based upon an assumption, the supporting assumption must be sufficiently grounded in sound methodology, and reasoning to allow the conclusion it supports to clear the reliability hurdle. Assumption-based conclusions that do not meet that test can hardly be relied upon as "good science."); see also Elcock v. Kmart Corp., 233 F.3d 734, 756 (3d Cir. 2000) (finding the district court abused its discretion in permitting an

[20] Nonetheless, Chintagunta also argues that econometric models are not sufficient to measure the impact of Cephalon's alleged off-label promotion because many of the factors that influence prescribing behavior are not appropriately measured at the aggregate level. (Chintagunta Rpt. ¶36.)

expert's testimony because the testimony was based on "several empirical assumptions that were not supported by the record.) Cephalon asserts that because Dr. Rosenthal's "causation assumption was provided by counsel" it is not "grounded in sound methodology." Plaintiffs seek to argue that Dr. Rosenthal was entitled to assume that all off-label prescriptions were caused by Cephalon's alleged off-label promotion. This, however, is not the relevant issue. The relevant issue is far narrower: whether Dr. Rosenthal was entitled to assume that all off-label prescriptions in excess *the precise amount of 15%* resulted from the allegedly illegal off-label marketing.

As Cephalon and its experts point out, the RMP merely calls for Anesta/Abbott/Cephalon to undertake certain remedial measures should off-label prescriptions of Actiq exceed 15% of total quarterly Actiq prescriptions. The RMP, however, expounds no obvious judgments as to why this off-label prescribing would occur. It only evidences the FDA's conclusion that off-label prescriptions in excess of 15% are, for unspecified reasons, intolerable. It remains unclear from this record through what means or for what reasons the FDA determined that off-label prescriptions in excess of 15% to be so intolerable so as to necessitate remedial measures. The Court is therefore inclined to agree with Cephalon that Plaintiffs and Dr. Rosenthal appear to have read quite a lot into the RMP's 15% trigger.

Nonetheless, the Court cannot find that Dr. Rosenthal's assumption "that there is a positive level of off-label prescribing that can result from clinical judgment by physicians, but this level of prescribing would not exceed 15% of total quarterly Actiq prescriptions absent the alleged misconduct" is so lacking in basis that her declaration and testimony must be excluded. Ideally, Dr. Rosenthal would have engaged in more rigorous examination in this final step of her

damages calculation. However, the fact remains that the 15% figure is derived from the FDA's RMP, and is not something that Plaintiffs or Dr. Rosenthal made up out of thin air. Given Rule 702's liberal policy of admissibility, the fact that the 15% threshold comes from the FDA is sufficiently "good grounds" to support Dr. Rosenthal's use of the threshold in her calculation. In re Paoli, 35 F.3d at 745-46.

C. Fit

Finally, in assessing the third requirement for the admissibility of expert testimony, the testimony's "fit," the Court must ascertain whether the testimony is "relevant for the purposes of the case" and whether it "assist[s] the trier of fact." Schneider, 320 F.3d at 404; see also Daubert, 509 U.S. at 591. This "helpfulness standard" requires a "valid scientific connection to the pertinent inquiry as a precondition to admissibility." Id. (quoting Daubert, 509 U.S. at 591-92).

Cephalon claims Dr. Rosenthal's opinion does not "fit" the claims in this case for two reasons. First Cephalon claims Dr. Rosenthal does not account for the "equities" which bear directly on whether any class member or group of class members is entitled to recover. Cephalon appears to consider the "equities" to be the differences amongst class members or the individual circumstances of any prescribing decision. The Court is unpersuaded by this argument, and has little difficulty in concluding that Dr. Rosenthal's testimony is relevant to this case. The "equities" that Cephalon emphasizes are essentially the same arguments Cephalon advances in opposing Plaintiffs' Motion for Class Certification. These arguments — while entirely relevant in determining whether Plaintiffs have met their burden of proving class certification should be granted — are not relevant to the question of whether Dr. Rosenthal's testimony would assist the trial of fact in measuring the Proposed Class's damages as a result of

Cephalon's alleged off-label promotion. Thus, Cephalon's contention that the "equities" must be considered is an argument best resolved in the context of Plaintiffs' Motion for Class Certification, not through the exclusion of Dr. Rosenthal's declaration and testimony.

Additionally, to the extent Cephalon contends Dr. Rosenthal's damages analysis does not "fit" the claims in this case because her analysis does not comport with the Supreme Court's decision in Comcast Corp. v. Behrend, 133 S. Ct. 1426, 185 L. Ed. 2d 515 (2013), it is mistaken. (See Def.'s Reply 2-6.) Comcast involved antitrust claims brought pursuant to Sections 1 and 2 of the Sherman Act. The Supreme Court reversed certification of a class of Comcast subscribers in the Philadelphia market. In doing so, the Supreme Court held that the plaintiffs had not met the predominance requirement of Federal Rule of Civil Procedure 23(b)(3) because they had not adequately demonstrated that damages were "susceptible of measurement across the entire class for Rule 23(b)(3) purposes." 133 S. Ct. at 1433. This was due to the fact that the plaintiffs in Comcast had presented four theories of antitrust impact, but the district court found only one of these theories was capable of class-wide proof. Id. at 1431. Problematically, however, the district court assumed damages could be measured on a class-wide basis even though the plaintiffs' expert's damages model was not tied to the specific liability theory certified. Id. The Supreme Court emphasized that "a model purporting to serve as evidence of damages in this class action must measure only those damages attributable to that theory." Id. at 1433. Here, unlike in Comcast, Plaintiffs assert only one theory of liability and Dr. Rosenthal's damages calculation is based solely on that theory: unjust enrichment. Thus, there is no comparable risk that Dr. Rosenthal's damages model "identif[ies] 'damages' that are not the result of" the alleged wrong. Id. at 1434.

Secondly, Cephalon contends Dr. Rosenthal's opinion does not "fit" because Dr. Rosenthal does not attempt to support Plaintiffs' alternative classes. Plaintiffs have proposed various alternative, state-based classes in the event the Court rejects nationwide class certification. Dr. Rosenthal, however, has not calculated damages based on Plaintiffs' alternative classes; rather, she has simply averred: "[i]f I am asked to do so by counsel, I can calculate damages by state using standard data and standard methods." (Rosenthal Decl. ¶10 n. 29); (see also Rosenthal Dep. 47:6-52:20.) Accordingly, Cephalon contends that Dr. Rosenthal's "untested promise to calculate damages on a state-by-state basis in the future is not enough to satisfy *Plaintiffs' class certification burden*." (Def.'s Mot. to Exclude 24) (emphasis added).

As Cephalon's own phrasing makes clear, Cephalon's argument is an issue best resolved in the context of the Motion for Class Certification. Until such time as the Court resolves Plaintiffs' Motion for Class Certification, Cephalon's argument is premature. Further, Cephalon arguably overstates the difficulty of calculating Cephalon's profits on a state-by-state basis. According to Dr. Rosenthal, the methodology for calculating net profits attributable to Actiq would not differ by state; rather, the only additional step would be apportionment of profits based on the percentage of sales of Actiq per state through publicly-maintained data. (Rosenthal Rebuttal ¶ 25.) Cephalon has not refuted Dr. Rosenthal's contention, and instead merely contends, essentially, that Dr. Rosenthal has not apportioned damages *yet*. Such a bare contention is insufficient. See In re Flonase Antitrust Litig., 284 F.R.D. 207, 233 (E.D. Pa. 2012); In re Wellbutrin SR Direct Purchaser Antitrust Litig., 2008 WL 1946848, at *9 (E.D.Pa. May 2, 2008) (reasoning that the court's inquiry is "limited to whether or not the proposed methods are so insubstantial as to amount to no method at all") (quoting In re Potash Antitrust

Litig., 159 F.R.D. 682, 697 (D. Minn. 1995); In re Vitamins Antitrust Litig., 209 F.R.D. 251, 268 (D.D.C.2002) ("At the certification stage, the preliminary inquiry in assessing the proposed methods of proving damages is limited: The inquiry is not whether the methods are valid, but is only to assess whether the methods are available to prove damages on a class-wide basis.").

IV. CONCLUSION

For the reasons set forth above, the Court finds that Dr. Rosenthal's declaration and testimony satisfy the qualification, reliability, and fit requirements of Rule 702 and Daubert. Accordingly, Cephalon's Motion to Exclude is denied. An appropriate order follows.